DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 2, 2015

Hamilton Medical AG
Ms. Frederike Brühschwein
Senior Manager Regulatory Affairs
Via Crusch 8
Bonaduz, Grisons, 7402
Switzerland

Re: K140939
Trade/Device Name: Hamilton-T1, Hamilton-C1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: July 28, 2015
Received: August 3, 2015

Dear Ms. Brühschwein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K140939

Device Name: **HAMILTON-T1**

Indication for Use: The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- For emergency medical care
- During transport within and outside the hospital
- During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE STATEMENT

510(k) Number: K140939

Device Name: **HAMILTON-C1**

Indication for Use: The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- During transfer of ventilated patients within the hospital

The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON·T1
HAMILTON·C1

510(k) SUMMARY

I. SUBMITTER

Hamilton Medical AG
Via Crusch 8
Bonaduz, 7402
Switzerland

Phone: +41 58 610 1568
Cell: +41 79 551 1151
Fax: +41 58 610 0020

Contact Person: Frederike Brühschwein, Senior Manager of Regulatory Affairs
Date Prepared: 2015-07-24

II. DEVICE

Name of Devices: HAMILTON-T1 and HAMILTON-C1
Common or Usual Name: Transport/ICU and +ICU ventilator
Device Classification and Name: 21 CFR 868.5895 Continuous Ventilator Device
Classification and Product Code: Class II CBK (incl. Class II DQA)

III. PREDICATE DEVICES

HAMILTON-T1 (K120670)	21 CFR 868.5895 Continuous Ventilator, Class II, CBK
HAMILTON-C1 (K120574)	21 CFR 868.5895 Continuous Ventilator, Class II, CBK
HAMILTON-C2 (K121225) for the neonatal modes.	21 CFR 868.5895 Continuous Ventilator, Class II, CBK
HAMILTON-G5 (K131774) for the Masimo SpO2 board and sensors	21 CFR 868.5895 Continuous Ventilator, Class II, CBK, (incl. Class II DQA)
MAQUET Servo-i (K073179) for the nCPAP and nCPAP-PC modes.	21 CFR 868.5895 Continuous Ventilator, Class II, CBK
Dräger Oxylog 3000 (K062267) for O2 consumption	21 CFR 868.5895 Continuous Ventilator, Class II, CBK

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The HAMILTON-C1 and HAMILTON-T1 are designed for adults, pediatrics, infants and neonatal patients requiring invasive or non-invasive ventilation support. Both ventilators cover a full range of clinical requirements: including invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and non-invasive ventilation.

The two previously cleared ventilators, the HAMILTON-T1 and the HAMILTON-C1, have been bundled together in this 510(k) submission, in order to add the following new features to both ventilators:

Neonatal patients with a minimum weight of 0.2 kg and a minimal tidal volume of 2 mL.
The following two new modes for the neonatal patient group: nCPAP and nCPAP-PC;
SpO2 monitoring with MASIMO PULSE OXIMETERS;
An increase in the battery duration from 5.5 hours on the HAMILTON-T1, to 9.25 hours (maximum) instead and an increased battery duration from 2 hours to 4.30 hours on the HAMILTON-C1.
Increased temperature range for the HAMILTON-T1 to 50°C [122°F] for adult and pediatric patients. Increased altitude operating condition for the HAMILTON-T1 from 15.091 ft to 25.000 ft for adult and pediatric patients.

V. INDICATIONS for USE for the HAMILTON-T1

The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room

- For emergency medical care
- During transport within and outside the hospital
- During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

VI. INDICATIONS for USE for the HAMILTON-C1

The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- During transfer of ventilated patients within the hospital

The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

VII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The HAMILTON-T1 and HAMILTON-C1 are substantially equivalent to the technology, and performance of the previous adult/pediatric version of the devices (HAMILTON-T1 with K120670 and HAMILTON-C1 with K120574).

The HAMILTON-T1 and HAMILTON-C1 are substantially equivalent to the intended use (including neonatal ventilation) of the HAMILTON-C2 (K121225).

The HAMILTON-T1 and HAMILTON-C1 are substantially equivalent to the SpO2 technology and to the use of SpO2 with the HAMILTON-G5 (K131774).

The HAMILTON-T1 and HAMILTON-C1 are substantially equivalent to the modes nCPAP-PC and nCPAP of the MAQUET Servo-I (K073179).

The HAMILTON-T1 is substantially equivalent to the O2 consumption monitoring and calculation of the Dräger Oxylog 3000 (K062267).

Table 1: Comparison of HAMILTON-T1 with predicates

	Predicate device: previous version of HAMILTON-T1	**Application device: HAMILTON-T1**	**Difference Status**
Indications for Use	The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use:	The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, **and optionally infants and neonates.**	The patient group infants and neonates is new. The substantial equivalence has been proven to the HAMILTON-C2 (K121225).

	Predicate device: previous version of HAMILTON-T1	Application device: HAMILTON-T1	Difference Status
	• In the intensive care ward or in the recovery room. • For emergency medical care or primary care. • During transport within and outside the hospital. • During transfer by rescue vehicles, jet or helicopter. The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	Intended areas of use: • In the intensive care ward, **intermediate care ward, emergency ward, long term acute care hospital** or in the recovery room • For emergency medical care • During transport within and outside the hospital • During transfer by rescue vehicles, **fixed wing aircraft**, helicopter or **ship.** The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications	
Product Classification Code	CBK	CBK	Identical
CFR Citation	21 CFR 868.5895	21 CFR 868.5895	Identical
Principal Operator	Qualified, trained personnel under	Qualified, trained personnel under the	Identical

	Predicate device: previous version of HAMILTON-T1	Application device: HAMILTON-T1	Difference Status
	the direction of a physician	direction of a physician	
Environment of Use	• In the intensive care ward or in the recovery room. • For emergency medical care or primary care. • During transport within and outside the hospital. • During transfer by rescue vehicles, jet or helicopter.	• In the intensive care ward, **intermediate care ward, emergency ward, long term acute care hospital** or in the recovery room • For emergency medical care • During transport within and outside the hospital • During transfer by rescue vehicles, **fixed wing aircraft**, helicopter or **ship**	Environment is identical, was only better specified
Environmental conditions	• 5 to 40 °C (41 to 104°F) • 10 to 95%, non-condensing • 1013 to 600 hPa (13.120 ft)	• 5 to **50°C** (41 to 122°F) for adults/pediatrics • **5 to 40°C (41 to 104°F) for neonates** • 10 to 95%, non-condensing • 1013 to **376 hPa (25.000 ft)** for adults/pediatrics **1013 to 600 hPa (13.120 ft) for neonates**	The components of the proposed device can withstand 50°C (122°F) in the adult/pediatric mode. The performance in high altitude has been increased for adult/pediatric patients to 376 hPa (25.000 ft)
Patient Interface	Delivered invasively (via ET tube) or non-invasively (via mask)	Delivered invasively (via ET tube) or non-invasively (via mask)	Identical

	Predicate device: previous version of HAMILTON-T1	Application device: HAMILTON-T1	Difference Status
Power Source	AC and DC; Battery powered with two batteries, can be run while battery is charging with a maximal run time of 5.5 hrs	AC and DC; Battery powered with two batteries, can be run while battery is charging with a maximal run time of **9.25 hrs**	Identical, battery time has been improved
Operational Modes	• ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST	• ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST • **nCPAP** • **nCPAP-PC**	New modes nCPAP and nCPAP-PC substantialy equivalent to MAQUET Servo-I (K073179).
SpO2 monitoring	No SpO2 monitoring	**SpO2** monitoring available	Substantial equivalence has been proven to the HAMILTON-G5 (K131774)
Active Exhalation Valve?	Yes, pneumatic	Yes, pneumatic	Identical
Size WxLxH (in)	8.3 x 12.2 x 9.4	8.3 x 12.2 x 9.4	Identical
Weight	14.3 lb	14.3 lb	Identical
Volume Setting Range	20-2000 ml	2-2000 ml	Volume can be set down to 2 ml for neonatal application; substantial equivalent to HAMILTON-C2 (K121225)
PEEP setting	0-35 cmH2O	0-35 cmH2O Neo: 3-25 cmH2O	Identical
Alarms and Monitoring	Yes	Yes	Identical

	Predicate device: previous version of HAMILTON-T1	Application device: HAMILTON-T1	Difference Status
Adjustable Inspiration Time total range	0.1-40 sec	0.1-40 sec	Identical
Supply Gas	Oxygen, ambient Air	Oxygen, ambient Air	Identical
Method of supply gas pressurization	Internal turbine for Air Compressed Source for O2	Internal turbine for Air Compressed Source for O2	Identical
MR Unsafe symbol	No	**Yes**	The proposed device now carries the "MR Unsafe" symbol according to ASTM F2503
O2 consumption monitoring	No	**Yes**	Substantial equivalence has been proven to the Dräger Oxylog 3000 (K062267)

Table 2: Comparison table of the HAMILTON-C1 with predicates

	Predicate device: previous version of HAMILTON-C1	Application device: HAMILTON-C1	Difference Status
Indications for Use	The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use: • In the intensive care ward or in the recovery room. • During transfer	The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates. Intended areas of use: • In the intensive care ward, **intermediate care ward, emergency**	The patient group infants and neonates is new. The substantially equivalency has been proven to the HAMILTON-C2 (K121225).

	Predicate device: previous version of HAMILTON-C1	Application device: HAMILTON-C1	Difference Status
	of ventilated patients within the hospital. The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	**ward, long term acute care hospital**, or in the recovery room • During transfer of ventilated patients within the hospital The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	
Product Classification Code	CBK	CBK	Identical
CFR Citation	21 CFR 868.5895	21 CFR 868.5895	Identical
Principal Operator	Qualified, trained personnel under the direction of a physician	Qualified, trained personnel under the direction of a physician	Identical
Environment of Use	• In the intensive care ward or in the recovery room. • During transport within and outside the hospital.	Intended areas of use: • In the intensive care ward, **intermediate care ward, emergency ward, long term acute care hospital**, or in the recovery room • During transfer of ventilated patients within the hospital	Environment is identical, was only better specified
Environmental	• 5 to 40 °C (41 to	• 5 to 40 °C (41 to	Identical

	Predicate device: previous version of HAMILTON-C1	Application device: HAMILTON-C1	Difference Status
conditions	104 °F) • 10 to 95%, non-condensing • 1013 to 600 hPa	104 °F) • 10 to 95%, non-condensing • 1013 to 600 hPa	
Patient Interface	Delivered invasively (via ET tube) or non-invasively (via mask)	Delivered invasively (via ET tube) or non-invasively (via mask)	Identical
Power Source	AC and Battery powered with one, can be run while battery is charging with a maximal run time of 2 hrs	AC and Battery powered with one battery, can be run while battery is charging with a maximal run time of **4.30 hrs**	Identical, battery time has been improved
Operational Modes	• ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST	• ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST • **nCPAP** • **nCPAP-PC**	New modes nCPAP and nCPAP-PC are substantially equivalent to MAQUET Servo-I (K073179).
SpO2 monitoring	No SpO2 monitoring	**SpO2** monitoring available	Substantial equivalence has been proven to the HAMILTON-G5 (K131774)
Active Exhalation Valve?	Yes, pneumatic	Yes, pneumatic	Identical
Size WxLxH (in)	8.3 x 12.2 x 9.4	8.3 x 12.2 x 9.4	Identical
Weight	10.8 lb	10.8 lb	Identical
Volume Setting Range	20-2000 ml	2-2000 ml	Volume can be set down to 2 ml for neonatal application;

	Predicate device: previous version of HAMILTON-C1	Application device: HAMILTON-C1	Difference Status
			substantial equivalent to HAMILTON-C2 (K121225)
PEEP setting	0-35 cmH2O	0-35 cmH2O Neo: 3-25 cmH2O	Identical
Alarms and Monitoring	Yes	Yes	Identical
Adjustable Inspiration Time total range	0.1-40 sec	0.1-40 sec	Identical
Supply Gas	Oxygen, ambient Air	Oxygen, ambient Air	Identical
Method of supply gas pressurization	Internal turbine for Air Compressed Source for O2	Internal turbine for Air Compressed Source for O2	Identical
MR Unsafe symbol	No	**Yes**	The proposed device now carries the "MR Unsafe" symbol according to ASTM F2503

Hamilton Medical has demonstrated the modified HAMILTON-T1 and HAMILTON-C1 ventilators to be substantially equivalent to currently marketed predicate devices that have been previously cleared by FDA.

VIII. PERFORMANCE DATA

The following performance and non-clinical data were provided in support of the substantial equivalence determination.

The Software Design and Validation process along with the bench testing of the device demonstrated that the HAMILTON-T1 and the HAMILTON-C1 operate as intended.

In particular, testing demonstrated that the HAMILTON-T1 and HAMILTON-C1 are compliant with the following guidelines and standards:

- FDA Draft Reviewer Guide for Ventilators (July 1995)
- ANSI/AAMI ES60601-1 (2005/ (R) 2012): Medical electrical equipment – General Requirements for Safety
- IEC 60601-1-2 (2007): Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- ISO 80601-2-12 (2011): Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- IEC 60601-1-8 (2006 + Am.1: 2012): Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-6 (2010 + A1 :2013): Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366 (2008)+A1(2014): Medical devices - Application of usability engineering to medical devices
- IEC 62304 (2006): Medical device software - Software life-cycle processes
- ISO 80601-2-55 (2011): Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

Additional Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Testing of the modified HAMILTON-C1 and HAMILTON-T1, with the new features, was conducted. The new ventilation modes were subjected to waveform performance testing, as described in the standard ASTM F1100-90. The data provided from these tests was shown to be substantially equivalent to the legally marketed devices.

Testing demonstrated that SpO2 and pulse rate values calculated by the OEM system are not corrupted during communication to the HAMILTON-T1 or HAMILTON-C1 host device. No modifications were made to the previously cleared pulse-oximeter systems.

The following additional testing was carried out to demonstrate substantial equivalence: Additional VOC and particular matters testing for the most vulnerable patient population: A gas sample analysis comprising VOC and particular matter testing has demonstrated that the output gas from the device meets the requirements for allowable levels of particulate matter.

IX. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-T1 and HAMILTON-C1 ventilators are as safe and as effective as the legally marketed devices identified above.